Appl. No. 09/996,555
Atty. Docket No. 8341
Amdt. dated 7 June 2004
Reply to Office Action of 23 September 2003
Customer No. 27752

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Currently Amended) A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal comprising:

a. a safe and effective amount of a therapeutically active agent;

b. an inner coating layer selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:2, poly(methacrylic acid, methyl methacrylate) 1:1, and mixtures thereof; and

c. an outer coating layer, applied directly to the inner coating layer, said outer coating layer comprising an enteric polymer ~~or film coating material~~ that begins to dissolve in an aqueous medium at a pH of less than about 7, said enteric polymer being selected from the group consisting of polymethacrylates, anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof;

wherein the inner coating layer is not the same as the outer coating layer;

wherein if the inner coating layer is poly(methacrylic acid, methyl methacrylate) 1:1 then the outer coating layer is not poly(methacrylic acid, methyl methacrylate) 1:2 or is not a mixture of poly(methacrylic acid, methyl methacrylate) 1:1 and poly(methacrylic acid, methyl methacrylate) 1:2; and

wherein the inner coating layer and the outer coating layer contain no therapeutically active agent.

Claim 2. (Original) The composition of claim 1 wherein the inner coating is poly(methacrylic acid, methyl methacrylate) 1:2.

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Claim 3. (Currently Amended) The composition of claim 1 wherein the outer coating layer is selected from the group consisting of ~~cellulose ethers, methyl cellulose, ethylcellulose, carboxymethylcellulose, carboxymethylethylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, low viscosity hydroxypropyl cellulose, low viscosity hydroxypropyl methylcellulose, wax, carnauba wax, fatty alcohols, hydrogenated vegetable oils, zein, shellac, sucrose, Arabic gum, polyethylene glycol, polyvinylpyrolidone, gelatin, sodium alginate, dextrin, psyllium husk powder, polymethacrylates, anionic polymethacrylates,~~ poly(methacrylic acid, methyl methacrylate) 1:1, and mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1~~, cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methylcellulose phthalate (HPMCP), cellulose propionate phthalate, cellulose acetate maleate, polyvinyl alcohol phthalate, hydroxypropyl methylcellulose acetate succinate (HPMCAS), hydroxypropyl methylcellulose hexahydrophthalate, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof~~.

Claim 4. (Currently Amended) The composition of claim 3 wherein the outer coating layer is a ~~selected from the group consisting of anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures~~ mixture of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1~~, cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methylcellulose phthalate (HPMCP), cellulose propionate phthalate, cellulose acetate maleate, polyvinyl alcohol phthalate, hydroxypropyl methylcellulose acetate succinate (HPMCAS), hydroxypropyl methylcellulose hexahydrophthalate, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof~~.

Claim 5. (Original) The composition of claim 1 wherein the total coating thickness of the inner and outer coating layers combined is from about 5 mg/cm^2 to about 40 mg/cm^2.

Claim 6. (Original) The composition of claim 5 wherein the total coating thickness is from about 10 mg/cm^2 to about 15 mg/cm^2.

Claim 7. (Original) The composition of claim 6 wherein the solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or cured.

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Claim 8. (Previously Presented) The composition of claim 1 wherein the therapeutically active agent is selected from the group consisting of laxatives, anti-diarrheals, nonsteroidal anti-inflammatory agents, 5-amino salicylic acid, glucocorticoids, antimicrobials, immunosuppressants, chemotherapeutics or anti-cancer drugs, peptides, proteins, cardiovascular drugs, psychotropic drugs, H2-blockers, antiasthmatic agents, and antihistamines.

Claim 9. (Original) The composition of claim 8 wherein the therapeutically active agent is a nonsteroidal anti-inflammatory agent.

Claim 10. (Previously Presented) The composition of claim 9 wherein the therapeutically active agent is 5-amino salicylic acid.

Claim 11. (Currently Amended) A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal comprising:

a. a safe and effective amount of a therapeutically active agent;
b. an inner coating layer comprising poly(methacrylic acid, methyl methacrylate) 1:2; and
c. an outer coating layer, applied directly to the inner coating, said outer coating layer comprising an enteric polymer ~~or film coating material~~ that begins to dissolve in an aqueous medium at a pH of less than about 7, said enteric polymer being selected from the group consisting of polymethacrylates, anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof;

wherein the inner coating layer is not the same as the outer layer coating.

Claim 12. (Cancelled)

Claim 13. (Cancelled)

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Claim 14. (Currently Amended) The composition of claim ~~13~~ **11** wherein the outer coating is selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:1 and mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.

Claim 15. (Original) The composition of claim **14** wherein the outer coating is a mixture of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.

Claim 16. (Original) The composition of claim **11** wherein the total coating thickness of the inner and outer coating layers combined is from about 5 mg/cm^2 to about 40 mg/cm^2.

Claim 17. (Original) The composition of claim **16** wherein the total coating thickness is from about 10 mg/cm^2 to about 15 mg/cm^2.

Claim 18. (Original) The composition of claim **17** wherein the solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or cured.

Claim 19. (Previously Presented) The composition of claim **11** wherein the therapeutically active agent is selected from the group consisting of laxatives, anti-diarrheals, nonsteroidal anti-inflammatory agents, 5-amino salicylic acid, glucocorticoids, antimicrobials, immunosuppressants, chemotherapeutics or anti-cancer drugs, peptides, proteins, cardiovascular drugs, psychotropic drugs, H2-blockers, antiasthmatic agents, and antihistamines.

Claim 20. (Original) The composition of claim **19** wherein the therapeutically active agent is a nonsteroidal anti-inflammatory agent.

Claim 21. (Previously Presented) The composition of claim **20** wherein the therapeutically active agent is 5-amino salicylic acid.

Claim 22. (Original) The composition of claim **11** wherein the solid dosage form is a compressed tablet.

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Claim 23. (Currently Amended) A method of consistent and reliable delivery and release of a therapeutically active agent to the desired region of delivery by orally administering the composition of claim ~~1~~ **1**.

Claim 24. (Currently Amended) A method of ~~consistant~~ consistent and reliable delivery and release of a therapeutically active agent to the desired region of delivery by orally administering the composition of claim ~~11~~ **11**.

Claim 25. (New) The composition of claim **1** wherein the solid dosage form is a compressed tablet.

Claim 26. (New) The composition of claim **1** wherein the solid unit dosage form has a total weight from about 600 mg to about 1200 mg.

Claim 27. (New) The composition of claim **10** wherein the 5-amino salicylic acid is present in an amount from about 700 mg to about 900 mg per solid unit dosage form.

Claim 28. (New) The composition of claim **1** wherein the outer coating layer has a minimum thickness from about 10 μm to about 200 μm.

Claim 29. (New) The composition of claim **4** wherein the outer coating layer has a minimum thickness from about 10 μm to about 50 μm.

Claim 30. (New) The composition of claim **29** wherein the outer coating layer has a minimum thickness from about 20 μm to about 40 μm.

Claim 31. (New) The composition of claim **11** wherein the solid unit dosage form has a total weight from about 600 mg to about 1200 mg.

Claim 32. (New) The composition of claim **21** wherein the 5-amino salicylic acid is present in an amount from about 700 mg to about 900 mg per solid unit dosage form.

Claim 33. (New) The composition of claim **11** wherein the outer coating layer has a minimum thickness from about 10 μm to about 200 μm.

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Claim 34. (New) The composition of claim **15** wherein the outer coating layer has a minimum thickness from about 10 μm to about 50 μm.

Claim 35. (New) The composition of claim **34** wherein the outer coating layer has a minimum thickness from about 20 μm to about 40 μm.

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